REMARKS

Claims1-7, 9, 11-15 and 57-64 are active in this application. Support for the hybridization conditions is found on page 5, lines 5-7. Support for Claim 57-64 is found in Claims 1-16 and the specification as originally filed. No new matter is added by these amendments.

Applicants wish to thank Examiner Nguyen for the courteous discussion granted to the Applicants' undersigned representative on February 7, 2003. During this discussion, amendments to address the rejections under 35 U.S.C. § 112, first paragraph were discussed,, and in particular, providing the stringent conditions. Therefore, in light of these amendments and the following remarks, Applicants request that Claims 9, 11-15 and 57-64 be allowed along with allowed Claims 1-6.

The rejections of Claims 7, 9 and 11-16 under 35 U.S.C. § 112, first paragraph are respectfully traversed.

Claim 9 has been amended to depend from the allowable Claim 1. Therefore, as the rejections apply to Claim 9 and 11-15, the rejections should be withdrawn.

Claim 7 (and claims dependent thereon) provide an isolated polynucleotide which hybridizes under stringent conditions to the complement of SEQ ID NO:1 or SEQ ID NO:3. The claims are enabled because the sequences are described, the conditions for hybridization are described, both on page 5, lines 5-7 and in the claim itself, and the activity of fertility associated antigen is described, see, for example, page 11, where the Applicants have described that FAA can stabilize sperm membranes and increase fertility.

With respect to the written description portion of this rejection, Applicants respectfully direct the Examiner's attention to the U.S. PTO "Synopsis of Application of Written Description Guidelines" and, in particular, Example 9 (a copy is attached for reference).

In this Example a situation that is analogous to Claim 7 is presented. The conclusion is that the claim in the Example, which is similar to Claim 7 in terms of providing for a sequence which hybridizes under stringent conditions to an allowable DNA, is adequately described. Thus, Claim 7 (and the claims dependent on Claim 7) is described because "a representative number of species is disclosed , since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention." (Example 9 of the "Synopsis").

In light of the above, Applicants request that the rejections under 35 U.S.C. § 112, first paragraph be withdrawn.

The rejection of Claim 7 under 35 U.S.C. § 112, second paragraph is obviated by amendment. Claim 7 is amended to provide the conditions for hybridization.

Applicants have now submitted a substitute Sequence Listing and a corresponding computer-readable Sequence Listing. A Sequence Identifier (SEQ ID NO:) has been added to the specification on page 9, lines 1-2. The sequence information recorded in the corresponding computer-readable Sequence Listing is identical to the paper copy of the substitute Sequence Listing. Support for all of the sequences listed in the substitute Sequence Listing is found in the present application as originally filed. No new matter is added.

Applicants submit that the present application is now in a condition for allowance.

Early notice of such allowance is kindly requested.

Respectfully submitted,

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#12

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

Contents

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

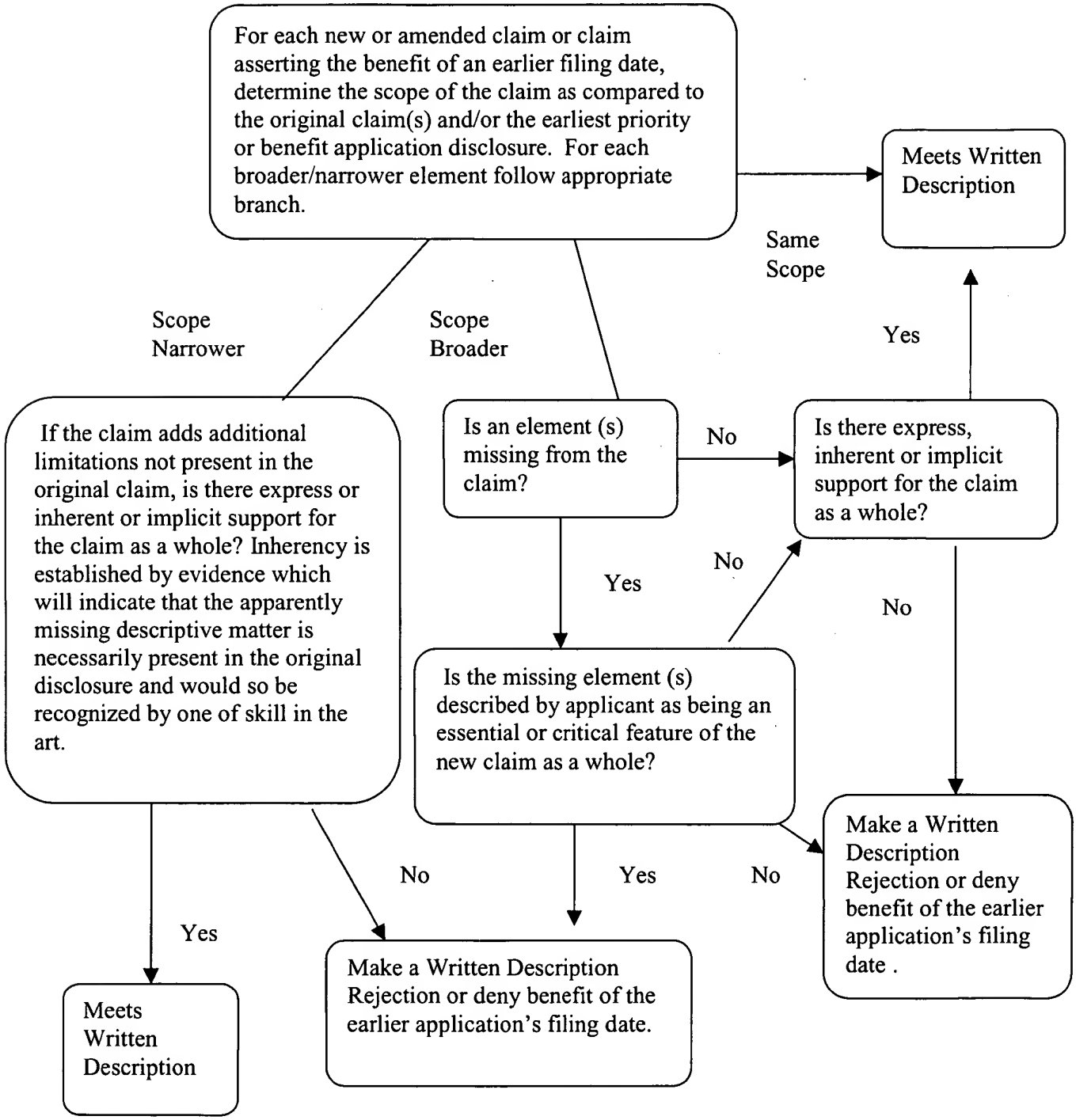
It is assumed at this point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that the examiner has identified which features of the claimed invention are conventional taking into account the body of existing prior art. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. If the examiner determines that the application does not comply with the written description requirement, the examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. It should also be noted that the test for an adequate written description is separate and distinct from the test under the enablement criteria of 35 U.S.C. § 112 first paragraph. The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, para. 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

The following examples only describe how to determine whether the written description requirement of 35 U.S.C. 112, para. 1 is satisfied. Regardless of

the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of Title 35 of the U.S. Code. Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

Written Description Amended or New Claims, or Claims Asserting the Benefit of an Earlier Filing Date

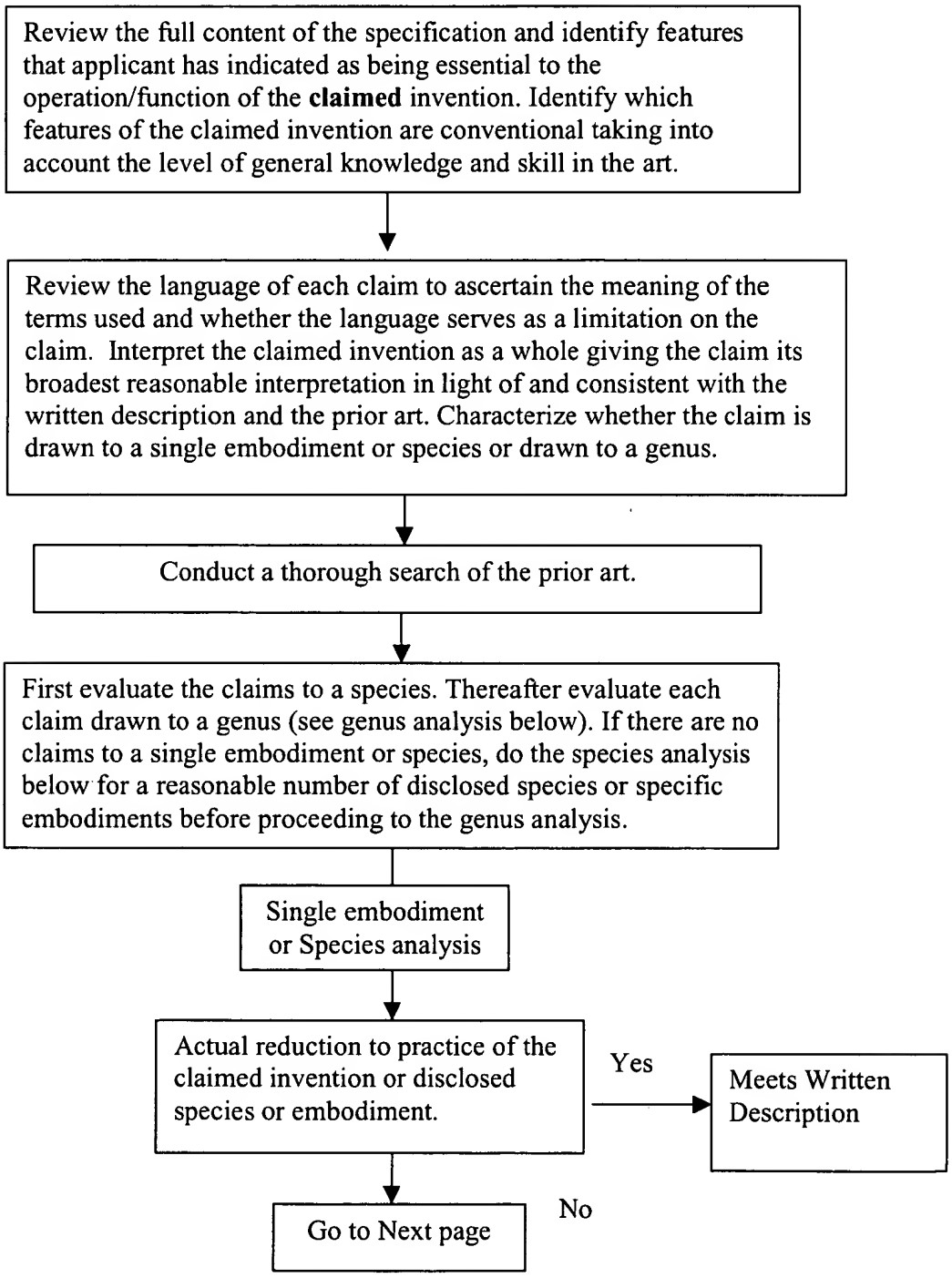
Decision Tree



Written Description

Original Claims

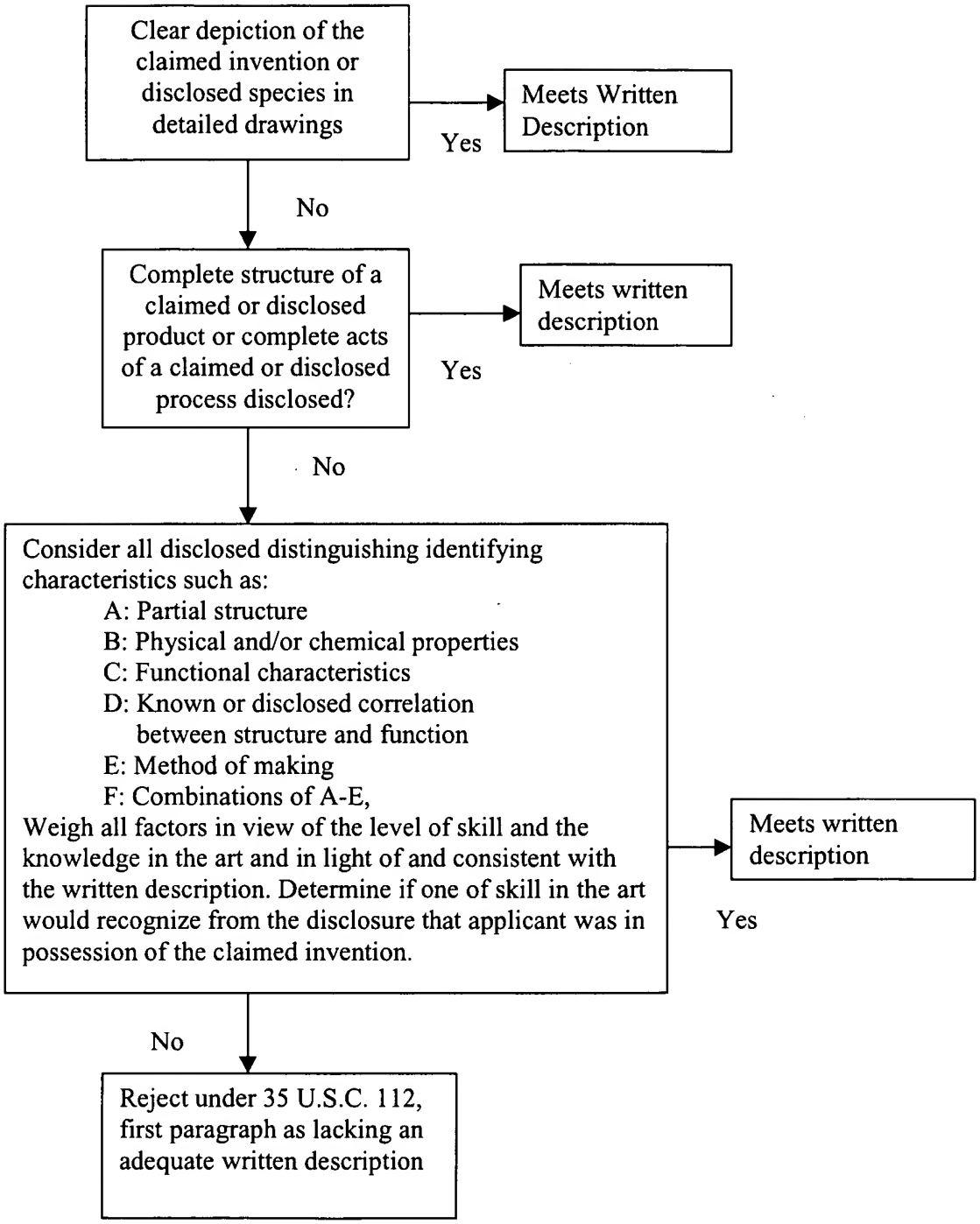
--Decision Tree--



Written Description

Original Claims

--Decision Tree--

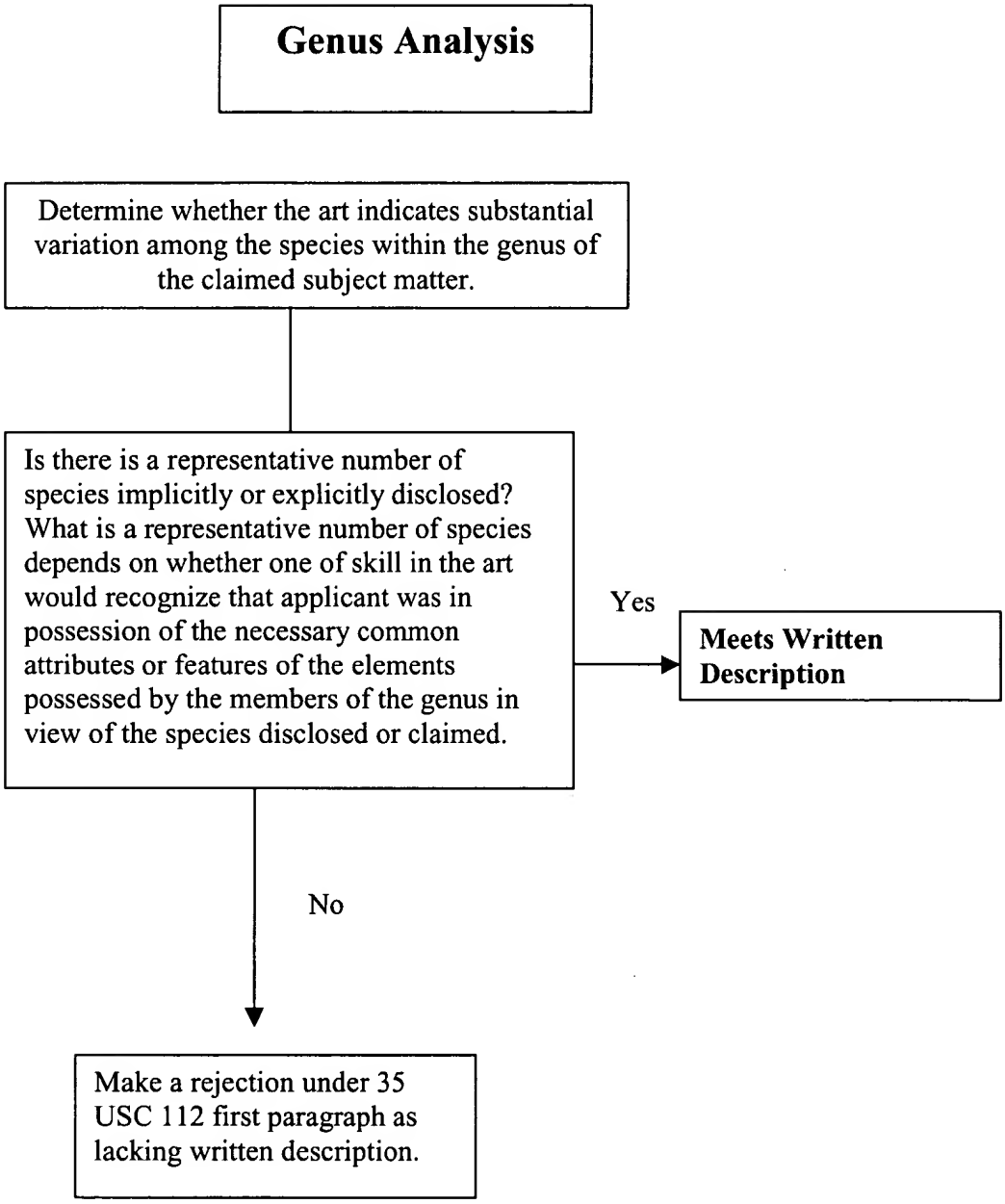


Written Description

Original Claims

Decision Tree

--Page 3--



e.g. expression vectors, the necessary common attribute is the ORF (SEQ ID NO: 2).

Weighing all factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2.

Conclusion: The written description requirement is satisfied.

Example 9: Hybridization

Specification: The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

Claim:

An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1,

wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

Analysis:

A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO: 1 under highly stringent conditions and encodes a protein with a specific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing.

The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity.

The search of the prior art indicates that SEQ ID NO: 1 is novel and unobvious.

There is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the claimed genus.

There is actual reduction to practice of the disclosed species.

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of

skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Conclusion: The claimed invention is adequately described.